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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,874	07/31/2003	Indranil Nandi	G-33302P1	1795

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/631,874	NANDI ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending in application

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lubitz (http://www.allergytriggers.com/treatments/medications/nose/allegra.htm) in view of Chhabra et al. (US 6,500,459 B1).

In claim 1, applicant claims "A pharmaceutical composition comprising fexofenadine or a pharmaceutical acceptable salt thereof, about 10 wt. % to about 70 wt. % of lactose, and about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition."

Lubitz discloses a pharmaceutical composition comprising fexofenadine HCl, lactose, and microcrystalline cellulose (see last line of page 1 to end of 1st paragragh of page 2).

Chhabra et al. disclose a pharmaceutical composition comprising an active ingredient and pharmaceutically acceptable excipients consisting of binders, fillers and lubricants (see abstract). Chhabra et al. also disclose that fexofenadine or its pharmaceutically acceptable salt can be the active ingredient of their composition (see col. 7, line 58 to col. 8, line 65 and especially col. 8, line 14) and that microcrystalline cellulose, lactose, hydroxypropyl cellulose can be used as the preferred binders and fillers (see col. 10, line 8 –18).

The difference between applicant's claimed composition and the composition disclosed by Lubitz is that applicant's composition contains hydroxypropyl cellulose whereas Lubitz composition contains microcrystalline cellulose, and Lubitz does not disclose specific wt. % of the components in the composition. However, Chhabra et al. disclose that microcrystalline cellulose, lactose, hydroxypropyl cellulose can be used as the preferred binders and fillers. This implies that hydroxypropyl cellulose or microcrystalline cellulose can be used. In addition, the use of specific wt. % of the components of said composition depends on the need, such as the individual to which this composition is administered.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Lubitz and Chhabra et al., to have prepared a pharmaceutical composition comprising fexofenadine HCl, lactose and hydroxypropyl cellulose of different wt. % to be used as an antihistamine composition, since Chhabra et al. disclose that hydroxypropyl cellulose can used in place of microcrystalline cellulose and the use of specific wt. % of the fexofenadine HCl, lactose and hydroxypropyl cellulose in said composition depends on need, such as the severity of the illness treated and the age and weight of the individual treated.

One having ordinary skill in the art would have been motivated in view of Lubitz and Chhabra et al., to have prepared a pharmaceutical composition comprising fexofenadine HCl, lactose and hydroxypropyl cellulose of different wt. % to be used as an antihistamine composition, since Chhabra et al. disclose that hydroxypropyl cellulose can used in place of microcrystalline cellulose and the use of specific wt. % of the fexofenadine HCl, lactose and hydroxypropyl cellulose in said composition depends on need, such as the severity of the illness treated and the age and weight of the individual treated. Claims 2-13 which are drawn to specific wt. % of the components of said composition, are also encompassed by this rejection. Claims 14-17 which are drawn to low-substituted hydroxypropyl cellulose of specific average particle sizes and wt. % are also rejected, since Chhabra et al. disclose does disclose any limitation on the type or particle size of the hydroxypropyl cellulose that can be used.

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chhabra et al. (US 6,500,459 B1).

In claim 18, applicant claims "A method of preparing a pharmaceutical composition comprising fexofenadine or a pharmaceutical acceptable salt thereof, about 10 wt. % to about 70 wt. % of lactose, and about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition, said method comprising:

(a) mixing fexofenadine, lactose, low-substituted hydroxypropyl cellulose, and optionally one or more excipients to form a premix;

(b) adding a solvent and optionally a surfactant to the premix formed in Step (a) to form a wet granulation; and

(c) drying the wet granulation to form dried granules;

(d) optionally milling the dried granules; and

(e) mixing at least one excipient with the dried granules to form a pharmaceutical composition."

Chhabra et al. disclose a method of preparing a pharmaceutical composition comprising an active ingredient (glipizide), said method comprising, blending the active ingredient with hydroxypropyl methylcellulose, adding polyethylene glycol dissolved in isopropyl alcohol (solvent) to form a granulation (which is wet), drying the wet granulation (granulated mass) at 60°C. for 3 hours, seiveing (or milling) the dried granules and lubricating the granules with talc (an excipient) (see col. 20, example 2 lines 25-45).

The difference between applicant's claimed method and the method disclosed by Chhabra et al. is that applicant's does not exemplifies the preparation of fexofenadine composition involving the use of lactose and hydroxypropyl cellulose in specific wt. %, per se. However, Chhabra et al disclose that fexofenadine or its pharmaceutically acceptable salt can be the active ingredient of their composition (see col. 7, line 58 to col. 8, line 65 and especially col. 8, line 14) and that lactose and hydroxypropyl cellulose can be used as the preferred binders and fillers (see col. 10, line 8 –18). In addition, the use of specific wt. % of of the components of said composition depends on the need, such as the individual to which this composition is administered.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to have used the method of Chhabra et al., to prepare a pharmaceutical composition comprising fexofenadine, lactose and hydroxypropyl cellulose of different wt. % to

be used as an antihistamine composition, since Chhabra et al. disclose that fexofenadine can be the active ingredient in the composition, hydroxypropyl cellulose and lactose can used as fillers and binders (i.e. excipients or inactive ingredients), and the use of specific wt. % of the fexofenadine, lactose and hydroxypropyl cellulose in said composition depends on need, such as the severity of the illness treated and the age and weight of the individual treated.

One having ordinary skill in the art would have been motivated in view of Lubitz and Chhabra et al., to have used the method of Chhabra et al., to prepare a pharmaceutical composition comprising fexofenadine, lactose and hydroxypropyl cellulose of different wt. % to be used as an antihistamine composition, since Chhabra et al. disclose that fexofenadine can be the active ingredient in the composition, hydroxypropyl cellulose and lactose can used as fillers and binders (i.e. excipients or inactive ingredients), and the use of specific wt. % of the fexofenadine, lactose and hydroxypropyl cellulose in said composition depends on need, such as the severity of the illness treated and the age and weight of the individual treated.

In claim 19, applicant claims "A method of preparing a pharmaceutical composition comprising fexofenadine or a pharmaceutical acceptable salt thereof, about 10 wt. % to about 70 wt. % of lactose, and about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition, said method comprising:

(a) mixing fexofenadine, lactose, low-substituted hydroxypropyl cellulose, and optionally one or more excipients to form a premix;

(b) adding a solvent and optionally a surfactant to the premix formed in Step (a) to form a wet granulation; and

(c) drying the wet granulation using a tray dryer to form dried granules;

(d) optionally milling the dried granules using a low shear mill; and

(e) mixing at least one excipient with the dried granules to form a pharmaceutical composition."

Chhabra et al. disclose a method of preparing a pharmaceutical composition comprising an active ingredient (glipizide), said method comprising, blending the active ingredient with hydroxypropyl methylcellulose, adding polyethylene glycol dissolved in isopropyl alcohol (solvent) to form a granulation (which is wet), drying the wet granulation (granulated mass) at 60°C. for 3 hours, seiveing (or milling) the dried granules and lubricating the granules with talc (an excipient) (see col. 20, example 2 lines 25-45).

The difference between applicant's claimed method and the method disclosed by Chhabra et al. is that applicant's does not exemplifies the preparation of fexofenadine composition involving the use of lactose and hydroxypropyl cellulose in specific wt. %, per se and does not use a tray drier to dry the granules. However, Chhabra et al disclose that fexofenadine or its pharmaceutically acceptable salt can be the active ingredient of their composition (see col. 7, line 58 to col. 8, line 65 and especially col. 8, line 14) and that lactose and hydroxypropyl cellulose can be used as the preferred binders and fillers (see col. 10, line 8 – 18). In addition, the use of specific wt. % of of the components of said composition depends on the need, such as the individual to which this composition is administered. And, it is obvious to use any common drying method (including a tray drier) to dry said granules.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to have used the method of Chhabra et al., to prepare a pharmaceutical

composition comprising fexofenadine, lactose and hydroxypropyl cellulose of different wt. % to be used as an antihistamine composition and to dry the granules by any common drying method, since Chhabra et al. disclose that fexofenadine can be the active ingredient in the composition, hydroxypropyl cellulose and lactose can used as fillers and binders (i.e. excipients or inactive ingredients), and the use of specific wt. % of the fexofenadine, lactose and hydroxypropyl cellulose in said composition depends on need, such as the severity of the illness treated and the age and weight of the individual treated, and it is obvious to use any common drying method (including a tray drier) to dry said granules.

One having ordinary skill in the art would have been motivated in view of Lubitz and Chhabra et al., to have used the method of Chhabra et al., to prepare a pharmaceutical composition comprising fexofenadine, lactose and hydroxypropyl cellulose of different wt. % to be used as an antihistamine composition and to dry the granules by any common drying method, since Chhabra et al. disclose that fexofenadine can be the active ingredient in the composition, hydroxypropyl cellulose and lactose can used as fillers and binders (i.e. excipients or inactive ingredients), and the use of specific wt. % of the fexofenadine, lactose and hydroxypropyl cellulose in said composition depends on need, such as the severity of the illness treated and the age and weight of the individual treated, and it is obvious to use any common drying method (including a tray drier) to dry said granules. Claim 20 which is drawn to a method according to claim 19 wherein the low shear mill is conical screen mill is also rejected by the aforementioned rejection, since it is obvious to use any milling or seiveing method to produce desired particle sizes of a composition, and Chhabra et al. disclose that the composition can be sieved (or milled) to produced desired particle size (see col. 20, example 2 lines 25-45).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

March 18, 2004.

SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1200